

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

**CHECKLIST FOR RESEARCH INVOLVING PREGNANT WOMEN
AND FETUSES**

Principal Investigator (please print):

Project Title:

1. Have scientifically appropriate, preclinical studies (including studies on pregnant animals) and clinical studies (including studies on nonpregnant women) been conducted that provide data for assessing potential risks to pregnant women and fetuses?

Yes ☐ No ☐

If "YES,"

- Is the risk to the fetus caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus?

Yes ☐ No ☐

OR

- If there is no prospect of benefit, is the risk to the fetus not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means?

Yes ☐ No ☐

2. Is the risk minimized as much as possible for achieving the objectives of the research?

Yes ☐ No ☐

3. Will informed consent be appropriately obtained?

Yes ☐ No ☐

4. For research of direct benefit solely to the fetus (not the pregnant woman), has informed consent been obtained from both the father and the mother?

Yes ☐ No ☐

If "NO,"

- Is the father unable to consent because of unavailability, incompetence, or temporary incapacity or did the pregnancy result from rape or incest?

Yes ☐ No ☐

5. For research of direct benefit to the pregnant woman, or of no direct benefit to either pregnant woman or fetus when the risk to the fetus is minimal and the purpose of the research is to develop important biomedical knowledge that cannot be obtained by other means, has informed consent of the pregnant woman been obtained?

Yes ☐ No ☐

CPHS *Use Only*

Project #: _____

Reviewer: _____

Date:

Rec: _____

To Rev: _____

From Rev: _____

Reviewer

Concurs:

☐ **Yes** ☐ **No**

☐ **Yes** ☐ **No**

☐ **Yes** ☐ **No**

☐ **Yes** ☐ **No**

☐ **Yes** ☐ **No**

☐ **Yes** ☐ **No**

☐ **Yes** ☐ **No**

☐ **Yes** ☐ **No**

CPHS *Use Only*

Project #: _____

**Reviewer
Concurs:**

☐ **Yes** ☐ **No**

☐ **Yes** ☐ **No**

☐ **Yes** ☐ **No**

☐ **Yes** ☐ **No**

6. For research in which the pregnant woman is a child, has assent been obtained from the child and permission from the child's parent(s) or guardians?

Yes ☐ No ☐

7. Have inducements, monetary or otherwise, not been offered to terminate a pregnancy?

Yes ☐ No ☐

8. Do individuals engaged in the research not have any part in decisions regarding timing, method, or procedures for termination of a pregnancy?

Yes ☐ No ☐

9. Do individuals engaged in research not play any part in determining the viability of a neonate?

Yes ☐ No ☐

Principal Investigator Signature: _____ **Date:** _____

CPHS Use Only

☐ **Approved** ☐ **Approval Deferred Pending Revisions** ☐ **Refer to Full Committee**

Comments:

Primary Reviewer Signature: _____ **Date:** _____

Checklist for Pregnant Women and Fetuses --12-11-03